UNOS
UNITED NETWORK FOR ORGAN SHARING
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CONFIDENTIAL MEDICAL PEER REVIEW

November 7, 2016

VIA SECURE EMAIL

[redacted]
Chief Executive Officer
Indiana Donor Network
[redacted]

[redacted]
Medical Director
Indiana Donor Network
[redacted]

Dear [redacted]

On October 27, 2016, the OPTN/UNOS Membership and Professional Standards Committee (MPSC) continued its review of Indiana Donor Network (INOP). As you know, on October 10, 2016, the MPSC reviewed the results of a routine site survey of INOP, including additional information on INOP's declaration of death and documentation. The MPSC Chair determined that this matter should be reviewed under the Expedited Review process described in the Bylaws, Appendix L.13. Based on its review, the MPSC, acting as an Expedited Review Committee, considered recommending that the Board of Directors refer INOP to the Secretary of Health and Human Services and declare INOP a Member Not in Good Standing.

This consideration entitled your OPO to an interview with the MPSC, which occurred on October 27. Your OPO submitted a plan for quality improvement, as well as additional information including a review of all donor brain death declarations, a description of staff, and staff training documentation, which the MPSC reviewed in preparation for the interview. The MPSC considered your OPO's file, statements by the representatives present at the interview, written records, and applicable provisions of the OPTN Final Rule, Bylaws and Policies. The MPSC also considered any supporting rationale, and generally accepted technical or scientific information that was relevant to the interview. A summary of the interview is included with this letter.

Based on its review and discussion of this issue, the MPSC approved the following:

> RESOLVED, that the Membership and Professional Standards Committee recommends that the Board of Directors place Indiana Donor Network on Probation for violation of Policy 2.2 (OPO Responsibilities).

[redacted]

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The Committee voted 21 For, 4 Against, and 1 Abstention.

The MPSC also requested that INOP provide the following:

- Continued monitoring of brain death declaration compliance
- Demonstration of the QAPI process and ongoing monitoring of policies
- A SWOT analysis of the process prior to and through brain death declaration for donors
- A description of what staff member has the responsibility to interact with physicians for the appropriate documentation of brain death, and who challenges the physician if they are not following the policy.
- Any activities in Hospital Development that relate to or include brain death declaration and testing information
- An evaluation of the current process including examining the roles of the Organ Procurement Coordinator (OPC) and the Family Services Coordinator (FSC)
- A review of job descriptions and expectations to ensure the appropriate qualifications are required
- A plan for competency assessment of FSCs to make sure that staff are performing as they are trained to perform.
- An evaluation of the process for training Administrators on Call (AOC) and ongoing competency assessment of AOCs
- A Hospital by hospital breakdown of institutions with ventilation capabilities, ICUs, and ORs
- A plan for culture change, with the Board of Directors and Advisory Board as active participants
- QAPI and Board meeting minutes
- Consider including a quality consultant from outside AOPO

MPSC Concerns

The MPSC is concerned that issues with brain death documentation represent a potentially severe risk to patient safety, the integrity of the transplant system, and the public trust. The MPSC noted that the OPO seemed to have detailed policies and training on brain death, but the records and documentation do not support that staff follow those policies. The MPSC is concerned that staff at INOP may have additional procedures that are not being followed, and without monitoring those issues would not be addressed. The MPSC also observed that since most of the OPO's staff and leadership have worked only at INOP, the OPO has not benefitted from knowledge of the same process at other OPOs.

The MPSC acknowledges that the OPO is passionate about organ donation, and that INOP has an experienced leadership structure and team. INOP reacted quickly and has responded to the review well; and the MPSC appreciates that the OPO takes this issue seriously.

Options and [redacted]

Probation, the Expedited Threat Review pathway, and the member's procedural rights when the MPSC is considering an adverse action are specifically defined in Appendix L of the Bylaws, which can be accessed on the OPTN website at [redacted]

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INOP has the following options:

1. Request a hearing. If your OPO wishes to exercise its right to a hearing, you must submit written notification to [redacted] Senior Compliance Operations Analyst, Member Quality Department by **5:00 pm EST on November 21, 2016,** via secure email to [redacted] or at the address in the letterhead using a method that can be tracked and provides proof of receipt.

   The Bylaws describe the hearing process. During a hearing you would be entitled to present any information relevant to the general nature of the organization's ability to comply with Bylaws and Policies. All materials about the institution that were considered by the MPSC, consisting of supplemental information furnished by the institution and copies of correspondence, will be made available to you upon request. If your institution submits a hearing request within the prescribed [redacted] period, UNOS staff will notify you of the hearing date, [redacted] and place. The hearing should convene no fewer than 7 days and no more than 60 days after receipt of the request. Your institution's representatives must be present to participate in the hearing, which may also include legal counsel. Please specify whether the OPO will be represented by counsel at the hearing and identify that counsel in the request for a hearing.

   After a hearing, the MPSC may issue a lesser action or continue to recommend Probation. If the MPSC continues to recommend Probation, your institution will have the right to appear before the Board of Directors.

   As specified in the Bylaws, the reasonable costs and expenses of conducting the hearing will be charged to the OPO. Such costs and expenses will include, but not be limited to, the travel and lodging expenses of the OPTN Contractor representatives; the court reporter fees and the cost of preparation of the necessary number of copies of the hearing record; the costs of obtaining and compiling evidence and exhibits; and the fees and expenses of the attorneys for the OPTN Contractor in preparing for and attending the hearing. If it is determined that your OPO is in violation of OPTN rules and requirements, the [redacted] costs associated with this hearing could be up to or exceed $125,000, depending on overall legal fees. Please note this amount may vary significantly as costs are incurred. This amount is provided to give you a general [redacted] of the potential expense. A binding decision as to the nature and total amount of the chargeable costs and expenses of the hearing will be made by the Presiding Officer after consultation with the Executive Director.

2. Decline the hearing and accept the adverse action of Probation. Your institution must acknowledge that it accepts this action by submitting written notification to [redacted] by **5:00 pm EST on November 21, 2016,** using a method described in item one above. The MPSC may then recommend that the Board move forward with the adverse action of Probation. Your institution would have the right to appear before the Board of Directors.

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If your institution waives both its right a hearing and accepts its right to appear before the Board of Directors, your appearance will take place at the Board of Directors meeting on December 5-6, 2016, in St. Louis, Missouri.

Should your institution not request a hearing or accept the adverse action in the manner described above, the institution is deemed to have waived its right to a hearing and the MPSC may continue to recommend that the Board of Directors place INOP on Probation.

You are reminded that this letter and all related documents comprise confidential medical peer review materials, which must be kept confidential by members during the review process and after the matter is closed. If you have any questions or concerns, or need any additional information regarding this resolution, please contact [redacted]

Sincerely,

[redacted]
Chair, OPTN/UNOS Membership and Professional Standards Committee

[redacted]
cc: [redacted] OPTN/UNOS Board of Directors
Brian M. Shepard, Executive Director and CEO, UNOS

Membership and Professional Standards Committee (MPSC)
Indiana Donor Network (INOP)
Interview Summary
October 27, 2016, Chicago, IL

MPSC Members Present: [redacted]

UNOS Staff Present: [redacted]

SRTR Staff Present: [redacted]

Indiana Donor Network Representatives Present: [redacted]

Interview Summary:
[redacted], MPSC Chair, convened the interview pursuant to Appendix L, Section L.17 of the Bylaws for the purpose of determining whether the Membership and Professional Standards Committee would recommend that the Board of Directors declare Indiana Donor Network a Member Not in Good Standing and refer the OPO to the Secretary of Health and Human Services for further action for violation of Policy 2.2 (OPO Responsibilities).

The Chair stated the Committee would consider Indiana Donor Network's file as well as the testimony and written evidence, applicable provisions of the Bylaws and Policies, including supporting rationale and generally accepted technical or scientific matters related to the issues under consideration. The Chair also stated the interview was being conducted under confidential medical peer review, and the entire interview and review process, including all related documents and information, are protected by applicable peer review statutes.

The President and Chief Executive Officer introduced herself and stated she has been with INOP for 16 years, with four in this role. She introduced the team and provided their background, their role, as well as their time with INOP. She then stated that the OPO came to discuss recent site survey results, with a focus on errors and failure points within the OPO's processes. The CEO stated that INOP recognizes and takes accountability for the OPO's responsibility to ensure

patient safety and public trust. The specific issues with brain death declaration required a fast response given the gravity and importance of this critical diagnosis to the integrity of the organ donation process. She acknowledged that the site survey process revealed systemic issues, and the OPO is committee to addressing these findings through an improved QAPI program over time.

The CEO continued that the primary focus of the presentation would be to address the three events related to brain death found on site survey. INOP has undergone rapid growth in the past three years, and strives to continually improve to serve families and patients in organ donation. This growth led to challenges with scalability, especially in the quality department.

Describing the issues found during the site survey, the CEO stated that OPOs are required to verify that brain death is pronounced according to applicable laws. In Indiana, that law is the Uniform Determination of Death Act which requires that death must be made in accordance with accepted medical standards. The OPO's policy prior to the site survey included a number of aspects to confirm pronouncement, but not the important components of an effective assessment for the diagnosis of brain death. This was a primary contributor to the lack of specificity and effectiveness of our brain death confirmation procedures. Of particular note, our previous policy relied on Family Services Coordinators (FSC) to review brain death documentation with the organ coordinator but without Administrator on Call (AOC) or Chief Medical Officer (CMO) involvement unless there was a specific question.

The CEO then described the details of the three cases found on the site survey. Each had slightly different documentation issues, but importantly all were not caught by the OPO's internal quality systems. In the first case, the OPOs records showed a note on admission to the ER that stated that the donor had a minimal gag reflex, and the brain death note used was made by a Nurse Practitioner. The CEO showed documentation that a physician did provide a separate brain death note and clinical exam, but this was not retained by the OPO as part of the donor record. The second case involved a donor with no documentation of a clinical exam consistent with brain death in INOP's donor record. The patient did have other studies, but a clinical exam was not performed in conjunction with the documentation of brain death or included in the OPO's records. The third case involved no documentation of confirmatory testing consistent with brain death in INOP's donor record. Each case had different concerns but there was a commonality in the failure of the OPO's internal quality assurance processes to recognize a deficiency.

As part of the QAPI program, the CEO said that the OPO performed a root cause analysis for these deficiencies as well as to determine why these errors were not caught by the quality assurance process. An external quality consultant, internal leadership members, and staff members identified failure points in the existing process including:

- Staff did not have access to the hospital policies for brain death.
- Besides general statements, no specific regulatory requirements that say brain death must be pronounced in a specific manner
- Pathways did not prompt front-line FSC or organ recovery coordinators (ORC) to ensure brain death verification and documentation was in compliance with internal or hospital policy.
- Pathways also did not require front-line FSCs or ORCs to verify brain death documentation by consulting with the AOC or CMO on every case.
- Internal Brain Death policy did not define proper methods to ensure proper brain death declaration.

- Organ Chart QA Process did not specify the information to be reviewed to ensure proper documentation, and there was no prompt to initiate a reportable event for missing documentation.
- Internal auditor did not identify these deficiencies in any of our internal audits.

Due to the severity of the violations and the necessity to ensure the integrity of the process, the OPO immediately contained this issue by significantly updating the brain death policy with direction from the Advisory Board. The CEO described that the OPO policy now indicates that the hospital must follow their policy on brain death declaration, but also includes minimum standards to be met. All documentation related to brain death testing must be obtained and verified to be in compliance with the hospital policy as well as our internal brain death policy. Staff then review the documentation with the AOC and CMO. The AOC has a brain death checklist that they must complete that includes all of the critical points previously mentioned.

The CEO stated that as part of the containment process the OPO performed a review of all organ hospital brain death policies and uploaded the most current version to the EMR for access by our staff. In collaboration with our CMO, the CEO sent letters to every organ hospital stating the need to be in compliance with their brain death policy but also informing them of updated practices and expectations moving forward. The letter also shared with the hospitals a sample best practice brain death policy as well as Indiana State Medical Association Guidelines for determining brain death. Since the internal policy and practice change which was effective October 6, the OPO has 100 percent compliance.

The CEO reported that the OPO educated all organ, family services, quality and professional services staff on the updated policy and new processes; the internal auditor added steps in several internal audits to verify compliance; and the OPO conducted competency and proficiency testing with all staff achieving 100% proficiency. In conjunction with the CMO, the OPO provided education to the AOCs on the updated processes to ensure those who were making decisions were competent, and the OPO will be reevaluating the annual competencies to ensure aptitude and adequate performance as required for each job function. Throughout this process, the OPO involved the executive leadership as well as the Advisory and Governing Boards.

Specifically, the CEO said that the Advisory Board met to review all deficiencies noted in the site survey and to discuss and provide recommendations on the brain death policy. Their recommendations were then reviewed with the executive committee of the governing board and approved for implementation. Further review and discussion will occur next week with the quality committee of our Board as well as at our next Advisory Board and Governing Board meetings.

As an added step, the Chief Operating Officer (COO) is also verifying the brain death process on every case with the AOC prior to the OR. The CEO stated that this process is not sustainable forever, but until the OPO has confidence in the new processes, they will continue to monitor the effectiveness of the systems. INOP intends to collect data showing how often the COO has had to ask for corrections, clarifications or changes to any of the cases.

Recognizing that there are experts in the field, the CEO said that the OPO has engaged three outside consultants in the containment and corrective action processes, including two AOPO site surveyors. It became evident through the evaluation that the OPO's internal variance reporting process was not effective. Moving forward, the OPO will be focusing on categorizing our variances and tracking and trending to identify, in real time, variances that cause to take immediate steps to contain issues and prevent recurrence. This data will be reviewed and discussed at internal quality committee meetings, with the Advisory Board, with the quality

committee of the Governing Board and with the entire Governing Board. The eventual goal of this improved occurrence reporting process is to become a more proactive organization over time by identifying issues before they become significant patient safety risks; such as the types revealed in the site survey results.

The CEO emphasized that INOP realizes they have significant work to do in this area and a culture change that must take place internally as well. They recognize that brain death pronouncement and documentation was only one piece of the site survey and that there is a systemic issue in relation to the quality department as there were several other areas identified as deficiencies in the survey. However, they felt it was paramount to address the brain death piece specifically to preserve patient safety and public trust.

The CEO stated that the Indiana Donor Network team is open to the peer review process and MPSC visits to ensure sustainability of the implemented processes as well as reporting to the MPSC on progress. In addition, staff plan to visit other OPOs to determine how they are handling some of the deficiencies noted, and to identify best practices. As the OPO continues to evolve and improve the QAPI program, they also plan to ensure involvement of the Advisory Board, quality committee, and Governing Board.

The CEO then thanked the members of the MPSC for the diligent and thoughtful review of the OPO's decisive actions. The OPO will continue its evolution as an organization and realizes that they have room to grow and improve with a diligent focus on a quality based culture.

The Chair thanked INOP for their presentation and opened the floor for questions.

A committee member thanked the OPO for a great presentation, and stated it was clear that they were taking this issue seriously. The committee member then asked whether the OPO involved a neurologist when reviewing the policies for brain death declaration, since there are some specific recommendations available for confirmatory tests. The CEO responded that they involved a retired neurosurgeon who sits on the Advisory Board, and the Governing Board Chair added that the neurosurgeon involved headed the committee that created the Indiana state guidelines both adult and pediatric brain death

The same committee member followed up with a question about educating a diverse OPO staff. The CEO acknowledged that their staff has diverse backgrounds, including human donation science programs, nurses, paramedics, and some with a background in grief. The OPO works with the CMO to develop training. The Manager of Organ Services stated that the staff is given a didactic presentation on brain death on the history, laws, clinical exam, and confirmatory testing; then the OPO supplements that with Cleveland Clinic's eLearning module. Staff have competency and physical assessment at least annually.

A committee member asked for a clarification on the brain death note by the nurse practitioner, and the CEO stated that the separate, later notes confirmed by the physician existed, but the OPO did not obtain copies prior to the donor OR.

In response to a comment on the quality of the presentation and a question about the seeming disconnect between the operational efficiency and the errors that occurred, the COO stated that the issues were a wake up call. The OPO had an issue with one of the primary roles of ensuring the integrity of the donation process, and found multiple discrepancies, so they wanted to fix the issue and find the root cause of how that happened. The COO continued that they responded first and foremost to accurately and quickly correct the process and make sure this never happens

again, but now they are engaging experts to continue to review and create a sustainable process so nothing like this happens again.

A committee member asked about any organizational changes in response to these never events. The CEO stated that the OPO had made changes in quality department before the site survey, as they recognized that they were not being efficient and had failures within their quality system. The OPO has a new Director of Quality. The OPO quality staff did not recognize that there was no consistent state law or procedure for brain death, and that they were not verifying that hospital policies were followed, just relying on the physicians to document.

A committee member asked how the OPO manages verifying 41 different hospital policies on brain death. The CEO replied that many of the policies are very different, with some are more detailed and very good. The OPO added a best practice policy and shared it with all hospitals to try make sure policies are somewhat consistent. At this point, the OPO has not received a lot of push back from hospital administration, but has met resistance from some from individual physicians.

In response to a question about lack of systemic insight and whether there are other issues that have not been discovered, the CEO stated that she would also have that question. The site survey showed missed documentation in other areas as well. The CEO explained that in the past the quality program has functioned as a medical records department rather than as a true quality assurance program, where staff have expertise in corrective and preventative actions, LEAN, and process improvement. The OPO is recruiting staff to work in that area that have that expertise. The CEO feels very confident that the OPO is paying close attention to key processes, and has audited other processes such as authorization and ABO verification to look for gaps.

A committee member asked whether the OPO had been reactive and was working to become more proactive, and should that have been recognized. The CEO responded that in certain areas they have been reactive, in others very proactive. The OPO uses a reportable events system, QPulse, to document any CAPA or nonconformance, and staff recognize and write reportable events all the time so that the appropriate action and follow up can prevent additional issues. The failure in this instance involved policies that were not very clear and direct about what had to happen for brain death declaration.

A committee member commented that the OPO has 12 FSCs, with a position description that does not require a clinical background, but states that they are responsible for collecting and communicating all information about medical suitability of the donor and investigating all concerns related to clinical information. She then asked whether having non-clinical staff in those roles came up during the RCA. The CEO responded that the OPO formerly required FSCs to be clinical, but sometimes there were others better suited to talking with families. She added that the FSC is not the only staff member reviewing the chart, ORCs are also on-site and initially evaluate the patient as well. Also, AOCs have remote access to medical records that they can access and review, as well as frequently contacting the CMO, even on initial referral. The OPO has not made the FSC clinical because they feel that resources are available to support.

The same committee member asked whether the Hospital Development staff and had a responsibility to ensure that hospitals have a brain death policy, donation policy, and other required policies; and to work to improve any that do not meet standards. The CEO said that the OPO has been working with several of the hospitals, over time, to develop better policies, and have met a lot of resistance. In this situation when, when there is investigation by other bodies, they comply without as much resistance. In the past there have been times where the OPO has

identified a case where they do not think the patient is brain dead, and if there is any question they will not move forward or will proceed as a DCD.

A representative from HRSA asked the CEO to confirm that the OPO has copies of policies from all donor hospitals, and to describe how they assure that each is following their policy. The CEO explained that all policies have been uploaded to their EMR system, so that the FSCs, ORCs, and AOCs access at beginning of every case. If the policy says that they perform a specific exam, the physician has to do it. If they miss one, OPO staff inform them. The AOC is also calling the COO and CMO for them to review cases, and staff have requested additional physicians to declare death if one is not following policy.

A committee member observed that it seems that the evaluation of declaration and compliance was not happening in real time, and questioned whether it is real-time now. The COO responded that INOP immediately consulted other OPOs to find out how they perform this task, and instituted a few functional steps. The OPO implemented the ORC talking to AOC, and both reviewing the hospital policy, OPO policy, and the chart to confirm compliance. The AOC has a checklist, then discusses the case with the COO and CMO to determine whether there are any issues that may come up. Two of those points were previously optional and now are mandatory. FSCs are also having a huddle with hospital staff to make sure that physicians are aware of what they need to do before declaration. The COO also described the OPO's DCD process for the committee.

A committee member asked the Board representatives to provide their perspective on the current situation. The Governing Board Chair said that the Board took the situation very seriously, and worked with the CEO to make sure that all Board members were aware, and to encourage follow through on the discussion and working through policy issues. He stated that to the OPO the donors and the families are the critical population they serve. The Advisory Board Chair added the he works with the Indiana Hospital Association, and is honored to be chair of the Advisory Board. The hospitals learn every day from the practices of INOP how to improve our functions as well. He has taken the new policy and requirements developed not just to the 41 hospitals but to all hospitals in Indiana, making CEOs and physicians aware that all need to have a good policy and provide them with sample policies.

The MPSC Chair asked for clarification of the delineation of 41 hospitals and other hospitals. The CEO responded that the state has a lot of hospitals that do not have ventilator capability, so in the event that they have cases, they transfer them. The OPO looked back at several years of donation to make sure to reach out to all involved hospitals.

He then observed that this happened even though the OPO had polices, procedures, and checklists, and asked how the OPO planned to change the culture. The CEO responded that unfortunately, in the past the attitude may have been that quality is the police, rather than being supportive and there to improve processes and prevent occurrences such as this. Many staff in the past have felt that reportable events are created to be punitive rather than for process improvement. In addition, the ORCs and FSCs are trained by one person passing information to another person. The OPO's failure was that they didn't identify that the process of relying on hospital expertise, and just making sure death was pronounced, wasn't sufficient. Also, most staff have not come from other OPOs, so the OPO did not have the benefit of anyone with experience suggesting a better practice. The OPO plans to try and share findings of this investigation with other OPOs, since there is likely a lot of process improvement possible.

With no further questions, the Chair thanked the program for their presentation.